Complete Summary

GUIDELINE TITLE

Overweight children and adolescents: a clinical report of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition.

BIBLIOGRAPHIC SOURCE(S)

Baker S, Barlow S, Cochran W, Fuchs G, Klish W, Krebs N, Strauss R, Tershakovec A, Udall J. Overweight children and adolescents: a clinical report of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. J Pediatr Gastroenterol Nutr 2005 May;40(5):533-43. [107 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Overweight and obesity

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Nursing
Nutrition
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

To present information on current understanding of the pathogenesis and treatment of overweight and obesity in children and adolescents

TARGET POPULATION

- Overweight and obese children and adolescents
- Children and adolescents at risk of becoming overweight or obese (prevention)

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Screening

1. Physical examination
2. Body mass index (BMI)
3. Evaluate for hypothyroidism, Cushing syndrome, or Turner syndrome (if short stature is associated with overweight)
4. Genetic evaluation (for the assessment of overweight associated with mental retardation [i.e., Prader-Willi, Laurence-Moon-Biedl, Cohen syndrome])
5. Fasting lipid profile
6. Fasting glucose levels
7. Liver function tests
8. Identification of overweight-related medical complications (depending on age, symptoms, and physical examination) such as hypothyroidism, hyperinsulinism, diabetes or polycystic ovary syndrome (thyroid function tests, luteinizing hormone levels, follicle-stimulating hormone, and testosterone, fasting insulin, and hemoglobin A1C)
9. Radiological testing (to diagnose slipped capital femoral epiphyses and Blount disease)

10. Assessment of readiness to address obesity

Management/Treatment

1. Establishment of realistic weight loss goals
2. Supportive family involvement
3. Dietary counseling
4. Physical activity and exercise programs
5. Limitation of sedentary behaviors
6. Implementation of recommendations of expert committees
7. Commercial weight loss programs
8. Intensive therapies for severely obese children
9. Protein sparing modified fast diets
10. Pharmacological treatment (orlistat, sibutramine; other drugs used in children with selective conditions)
11. Gastric bypass surgery
12. Emotional support

Primary Prevention

1. Interventions to prevent obesity

MAJOR OUTCOMES CONSIDERED

- Body mass index
- Weight loss
- Quality of life
- Morbidity associated with obesity and related co-morbidities

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

<u>Background</u>

Definition

The Centers for Disease Control and Prevention (CDC) recommends using the percentile body mass index (BMI) for age and gender as the most appropriate and easily available method to screen for childhood overweight or at risk for overweight. BMI is calculated by dividing the weight in kilograms by the height in meters squared. Age and gender norms for BMI are readily accessible. BMI correlates with adiposity and with complications of childhood overweight such as hypercholesterolemia, hypertension and later development of cardiovascular disease. Although more precise measures of lean body mass and body fat such as dual x-ray absorptiometry (DEXA) may be appropriate for clinical studies, BMI

norms are particularly helpful for screening in busy office practices and for population assessment.

Because BMI norms for youth vary with age and gender, BMI percentiles rather than absolute BMI must be determined. The cutoff values to define the heaviest children are the 85th and 95th percentiles. In adolescence as maturity is approached, the 85th percentile roughly approximates a BMI of 25, which is the cutoff for overweight in adults. The 95th percentile roughly approximates a BMI of 30 in the adolescent near maturity, which is the cutoff for obesity in adults. The cutoff recommended by an expert committee to define overweight (BMI $\geq$95th percentile) is a conservative choice designed to minimize the risk of misclassifying nonobese children.

Refer to the original guideline document for further background information on the molecular biology and epidemiology of obesity and the persistence of overweight and obesity into adulthood.

Medical Conditions Associated with Childhood Overweight and Obesity

Laboratory tests and radiologic examinations are rarely helpful for diagnosing the causes of overweight. However, short stature associated with overweight may indicate the need to evaluate for hypothyroidism, Cushing syndrome, or Turner syndrome. A genetic evaluation may be helpful in the assessment of overweight associated with mental retardation (i.e., Prader-Willi, Laurence-Moon-Biedl, Cohen syndrome). Fasting lipid profile and fasting glucose should be performed in obese or overweight children. Liver function tests should be obtained because steatosis or steatohepatitis is generally asymptomatic. Depending on age, symptoms, and physical examination, many patients will require thyroid function tests and measuring luteinizing hormone, follicle-stimulating hormone, and testosterone, fasting insulin and hemoglobin A1C to identify overweight-related medical complications such as hypothyroidism, hyperinsulinism, diabetes, or polycystic ovary syndrome. Radiological testing is necessary to diagnose slipped capital femoral epiphyses and Blount disease.

Gastrointestinal Conditions Associated with Childhood Overweight and Obesity

Refer to the original guideline document for a discussion of gallstone and non-alcoholic fatty liver disease (steatosis and steatohepatitis) in overweight and obese children.

Because other chronic liver diseases can occur in obese children, elevations in liver chemistries in obese children should prompt the same evaluation for etiologies of chronic liver disease that would be performed in children of normal weight. In particular, Wilson disease may cause elevated liver enzymes as well as steatosis. Obese children with persistently elevated serum transaminases, particularly those whose elevations remain over twice normal, require liver biopsy to exclude other causes of liver pathology and to determine the presence and severity of fibrosis or cirrhosis in those with steatohepatitis.

Treatment

Comprehensive Programs: Diet, Exercise, and Behavior Modification

Superficially, it would seem that the treatment of overweight is straightforward: counsel children to eat less and be more physically active. In practice, treatment of childhood overweight is time-consuming, frustrating, difficult, and expensive.Comprehensive programs that include counseling on dietary, behavioral, and activity changes can be successful, although the critical support systems to help sustain changes in behavior are often lacking.

Readiness

At the outset it is important to assess the level of concern of each family member about the child's weight. If one parent remains unconcerned, mixed messages will be sent to the child that can confound treatment. Many families welcome an opportunity to address the problem of overweight or obesity in their children. However, some families may be unwilling or unable to make necessary changes; some families are unconcerned about their child's weight; other families may feel that the excess weight is inevitable or that personal circumstances make eating and activity changes too difficult. Because lack of readiness may lead to failure, frustration, and reluctance to address the problem in the future, deferring treatment or referral until the family is ready to make changes may be appropriate. Physicians can use the Stages of Change model to increase a family's readiness. For instance, if a family is not concerned about obesity, then education about current medical conditions or risks in the family could move the family from precontemplation to contemplation.

Treatment Goals

Individuals presenting to weight treatment centers usually have expectations of weight loss that far exceed what can be realistically achieved. For instance, the typical adult patient presenting for weight loss desires to lose 75 pounds. Unrealistic goals concerning weight loss or changes in exercise habits and eating patterns can undermine the child's confidence and reinforce a fatalistic attitude towards the child's weight problem. Unrealistic expectations may contribute to dropout and relapse in those who successfully make dietary and behavioral changes.

Children in behavioral weight programs tend to lose between 4 and 15 pounds. For the growing child, weight maintenance is often an achievable, realistic goal. Weight maintenance is always the first goal. In addition, children and their families need to recognize that sustainable weight loss of as little as 5% to 10% results in significant improvement in cholesterol, blood pressure, and blood glucose.

Family Involvement

Treating overweight involves understanding the eating and activity habits of the entire family. Parents buy the food, cook the food, and model eating patterns. Parents also provide access to activities and either encourage or discourage television viewing. Therefore, changing eating and activity habits is an active process involving the entire family. Such changes demand considerable conscious effort and support. Parents need to provide access to healthy, nutrient-dense

foods and snacks and opportunities for the child to increase physical activity. Parents can reinforce positive eating and activity behaviors with rewards not based on food, money, or gifts. Unfortunately, many families have difficulty identifying non-monetary, non-food rewards. A typical reward could involve quality family time such as a family outing to a park or playground (see Table 2 in the original guideline document for suggested non-food rewards). Rewards are generally recommended for diet and physical activity change rather than for weight loss. Praise is an essential component for changing children's attitudes and behaviors. Family dynamics are also important. It is vital that children be offered consistency. Children of divorced parents who live in two households may become confused if one household supports treatment and the other does not. Similarly, grandparents must be willing to support the treatment.

A family therapist or behavioral psychologist is often necessary to facilitate change. In university-based programs, psychological counseling is usually available. In office-based practices, it may be necessary to network with local psychologists to find a counselor interested, empathetic, and skilled in behavioral management techniques and family counseling. Most successful weight control programs use behavior modification techniques to reduce caloric intake and increase activity. Commonly used strategies to change behavior include self-monitoring of eating and activity, modification of the environment to decrease stimuli for eating or inactivity, and positive reinforcement for new behaviors.

Dietary Counseling

Instead of focusing on dietary restriction, dietary counseling is aimed at improving the nutritional quality of the diet. A common sense approach to eating is recommended (See Table 3 of the original guideline document). Parents should take charge of meal times and food choices but should not force children to eat certain foods. Sit-down meals involving the entire family and without distractions such as television are ideal. In this way, dinnertime is not just about eating but also involves discussions of the day's events and building relationships.

Children should not be placed on "fad" diets. A low saturated fat, moderate total-fat diet ($\leq$30%) with five fruits and vegetables a day is consistent with the food guide pyramid and is generally recommended. High-fiber foods and avoidance of highly refined starches and sugars are also likely to decrease caloric intake. Although counting calories is tedious and unreliable, self-monitoring of intake may help children learn to eat only when they are hungry and also help them to focus on which foods they choose to eat. Reviewing school lunch menus and helping parents identify low-fat school lunch selections may also result in healthier food choices by the child. In some cases a structured diet, which does not forbid any foods but balances the amount of high and low calorie foods, is appropriate. A dietitian can provide specific instructions for the diet.

Physical Activity and Exercise

Any form of increased physical activity is beneficial, provided that activities are age-appropriate and enjoyable. In postpubertal children, weight training increases lean body mass, which can result in increased basal metabolic rate. Fat loss associated with weight training may sometimes be counterbalanced by increased muscle mass. Weight training is generally not recommended for prepubertal

children unless proper resistance training techniques and safety precautions are followed. Preadolescents and adolescents should avoid competitive weight lifting, power lifting, body building, and maximal lifts until they reach physical and skeletal maturity. Aerobic exercise and endurance training increase the ability to oxidize fats. Light exercise such as walking provides valuable family time together and increased caloric expenditure.

The best form of activity is any form that is sustainable. For prepubertal children, simply increasing time spent in free play, especially outdoors, is likely to be beneficial. Activity or exercise programs can be designed to increase the interaction between parents and children (e.g., playing basketball with a parent or family walks) or with other children (e.g., participating in karate with a friend).

Limiting sedentary behaviors such as television viewing may be the most effective way to facilitate physical activity and weight loss in children. The American Academy of Pediatrics recommends limiting television viewing to 1 or 2 hours per day. Table 4 in the original guideline document lists strategies to increase physical activity.

Recommendations of Expert Committees

Faced with an epidemic of childhood obesity but incomplete data on the most efficacious treatment, the Maternal and Child Health Bureau, Health Resources and Services Administration convened a committee of experts in childhood overweight to provide those who care for children with practical directions on evaluation and treatment of overweight children. Health care providers can apply these recommendations to address obesity in an office visit. However, clinicians must consider each family's circumstances when they recommend changes; neighborhood safety, parents' work schedules, and family finances will affect eating and activity options. The table below, titled "General Approach to Therapy," presents the committee's general approach to treatment. Because parents are responsible for instituting eating and activity changes, they need support and guidance in basic parenting skills, summarized in Table 6 of the original guideline document.

Table: General Approach to Therapy

- Intervention is to begin early
- The family must be ready for change
- Clinicians should educate families about medical complications of overweight
- Clinicians should involve the family and all caregivers in the treatment program
- Treatment programs should institute permanent changes, not short term diets or exercise programs aimed at rapid weight loss
- As part of the treatment program, a family is to learn to monitor eating and activity
- The treatment program should help the family make small, gradual changes
- Clinicians encourage and empathize, but not criticize
- Treatment goals need to be clearly established (improved healthy eating choices, increased levels of activity, decreased sedentary, behaviors, less "food fights," improved self-attribution)
- Establish realistic weight goals

- Clinicians need to identify and address issues concerning body image, self-esteem, depression teasing, and family conflicts about weight

Adapted with permission from Barlow, SE, Dietz, WH. Obesity evaluation and treatment: expert committee recommendations. Pediatrics. 1998;102:E29.

Commercial Weight Loss Programs

Many medical centers offer self-pay programs for weight control or weight loss in children. Participants generally meet in groups weekly for approximately 3 months and receive guidance in eating, activity, and behavior modification. Parents usually participate in sessions with their children or in parallel sessions for parents.

Some adolescents participate in commercial adult weight loss programs, although studies of the effectiveness of these programs in teens have not been performed. Of concern is that the personal and emotional issues related to eating and obesity discussed in these programs are generally targeted towards adults rather than adolescents.

Intensive Therapies for Severely Obese Children

In rare circumstances, adolescents with marked obesity benefit from rapid weight loss. Aggressive weight loss therapy includes restrictive dieting, pharmacological therapy, or even surgery. Potential physiologic harm from rapid weight loss from any of these therapies include slowing or cessation of linear growth, loss of lean body mass, inadequate nutrient intake, and gallstones.

Protein-Sparing Modified Fast

Patients with severe obesity may benefit from strict diets such as the protein-sparing modified fast, a hypocaloric, ketogenic diet designed to provide enough protein to minimize loss of lean body mass during weight loss. The patient consumes 1.5 to 2.5 g of protein per kilogram of ideal body weight each day, which is the equivalent of 6 to 10 g of lean meat or fish per kilogram of ideal body weight. The protein intake can be in the form of a protein drink. Intake of carbohydrate must be low enough to maintain ketosis.

Complications include protein losses, hypokalemia, hypoglycemia (particularly in the very young), inadequate calcium intake, and orthostatic hypotension. Potassium and calcium supplementation and adequate calorie-free fluid intake can minimize these complications.

Such diets should only be implemented in conjunction with a multidisciplinary team including an experienced physician, nutritionist, and behavioral (or family) therapist. Overall, protein-sparing modified fast regimens seem reasonably effective when performed under medical supervision and result in more rapid weight loss than conventional dietary and behavioral therapy, at least in the short term. Results establishing long-term beneficial outcome after protein-sparing modified fast are not available.

Pharmacological Treatment

Randomized placebo controlled trials in obese adults demonstrate modest but significant benefit of pharmacological interventions. The two drugs most carefully evaluated are orlistat and sibutramine. In clinical trials of these drugs, subjects also received education and behavior modification to increase physical activity and decrease calorie intake. Orlistat, an enteric lipase inhibitor, blocks absorption of approximately 30% of dietary fat and has recently been approved for use by children aged 12 to 16 years in conjunction with a reduced-calorie diet. The recommended dose of orlistat is 120 mg three times per day with meals. A multivitamin containing fat-soluble vitamin should also be taken because orlistat can reduce absorption of these vitamins.

Other available prescription appetite suppressants include phentermine and phendimetrazine, but these are not approved by the United States Food and Drug Administration for long-term use. Even in the best circumstances, medications such as orlistat, sibutramine, or phentermine generally produce only modest weight loss of 3% to 8% compared with placebo; however, a subset of patients may achieve more substantial weight loss. In general, use of Food and Drug Administration approved prescription medications in children awaits studies of safety and efficacy.

Other drugs have been used to produce weight loss in children with selective conditions: metformin in obese adolescents with insulin resistance and hyperinsulism, octreotide for hypothalamic obesity caused by intracranial tumors, growth hormone in children with Prader-Willi Syndrome and leptin for congenital leptin deficiency. Such medicines are not appropriate for general use in overweight children.

Gastric Bypass Surgery

There are few data on bariatric surgery in obese adolescents and none in younger children.

As in adults, a multidisciplinary team with medical, surgical, nutritional, and psychological expertise carefully selects adolescents for gastric bypass. All severely obese children more than 100% above ideal body weight are first provided the opportunity to lose weight through a family-based dietary and behavioral program as recommended by the Expert Committee on Obesity Evaluation and Treatment. Until more data are available in children, gastric bypass surgery should be considered only for well-informed and motivated adolescents who meet the following criteria: severe obesity (BMI $\geq$40), failure of $\geq$6 months of organized attempts at weight loss, near-complete skeletal maturity, and significant comorbidities that would be responsive to sustained weight loss. Extensive counseling, education, and support are required both before and after gastric bypass. Only a surgeon with extensive experience with bariatric surgery should perform gastric bypass surgery. Finally, adolescents undergoing gastric bypass require lifelong medical and nutritional surveillance, especially during pregnancy.

Emotional Support

Few problems in childhood have as significant an impact on emotional development as being overweight.

Institution of dietary modification and activity counseling without addressing issues of self-esteem, depression, anger, shame, and humiliation may undermine treatment. A child who successfully loses weight will not automatically feel less depressed, make more friends, have better self-esteem, or stop arguing with parents. Unanticipated persistence of negative self-feelings may undermine the child's and family's motivation. Therefore, psychological counseling specifically targeting emotional feelings of low self-worth, depression, and shame is an essential part of treatment for obese children and adolescents.

Parents can increase a child's self-esteem by giving the child positive, supportive messages that promote learning, decision making and self-confidence. Regular physical activity may also help increase self-esteem.

Primary Prevention of Childhood Overweight and Obesity

The most logical approach to weight control in childhood is prevention. Until a child enters school, their weight reflects the eating and activity environment provided by parents or other caregivers. While in school, a child can be influenced by what is taught about diet and activity as well as what is offered for meals and exercise. Habits that develop in childhood profoundly influence activities later in life. Although the current environment that promotes high calorie intake and sedentary lifestyle is an important contributor to the obesity rates in the United States, interventions to change that environment will meet many social and financial barriers. At present, prevention of childhood obesity and subsequent persistence of obesity into adulthood may be a more effective means to improve the obesity levels in the United States. If the epidemic of childhood overweight and obesity cannot be halted, its full impact will not be felt until current children become adults. It is important to realize that even though obesity in the adult population is at epidemic proportions, when present adults were children the prevalence of overweight in children was less than half of what it is now.

Conclusion

The current increase in childhood overweight and obesity reflects the convergence of many biologic, economic, and social factors. Body mass index is a quick and easy way to screen for childhood overweight. Although genetic differences may result in subtle differences in metabolism that predispose an individual to becoming overweight or obese, no measurable differences in metabolism can be detected in the majority of obese children. With increasing frequency, serious medical sequelae of overweight have their onset during childhood rather than the adult years. The social and emotional aspects of overweight are immediate and apparent and influence many aspects of child and adolescent well-being independent of their physical health effects.

The solution for the current epidemic of overweight and obesity is prevention. Screening of children for overweight should begin in the first year of life, and primary care practitioners can monitor the nutritional status of children in their practice by calculating and plotting body mass index (BMI) once standing heights are obtained after 2 years of age. Advice should be offered to parents regarding the prevention of overweight as soon as a child begins to cross BMI percentiles and should not be postponed until the child or adolescent is at or above the 95th percentile of BMI for age and gender.

Although the treatment of overweight in children is not simple, fast or invariably successful, controlled studies of obese children have demonstrated good short-term and long-term outcomes. Treating childhood overweight relies on positive family support and lifestyle changes involving the whole family. Preconceived notions about dieting and weight loss often confound treatment. Parental and childhood education is, therefore, essential. When the right family dynamics exists--a motivated child with supportive parents--success is possible.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate interventions for overweight children can improve quality of life, self-image, and overall physical health and decrease or prevent weight-related comorbidities.

POTENTIAL HARMS

- Potential physiologic harm from rapid weight loss include slowing or cessation of linear growth, loss of lean body mass, inadequate nutrient intake, and gallstones.
- Side effects of pharmacological agents used for weight loss
- Complications associated with the protein-sparing modified fast diet include protein losses, hypokalemia, hypoglycemia (particularly in the very young), inadequate calcium intake, and orthostatic hypotension.
- Side effects associated with gastric bypass surgery may include gallstones, adhesions, abdominal-wall hernia, micronutrient deficiency (i.e., folate, B12, fat-soluble vitamins, iron), and anemia.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Baker S, Barlow S, Cochran W, Fuchs G, Klish W, Krebs N, Strauss R, Tershakovec A, Udall J. Overweight children and adolescents: a clinical report of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. J Pediatr Gastroenterol Nutr 2005 May;40(5):533-43. [107 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 May

GUIDELINE DEVELOPER(S)

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition - Professional Association

SOURCE(S) OF FUNDING

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

GUIDELINE COMMITTEE

Childhood Overweight Working Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Working Group Members: Susan Baker, Buffalo, NY; Sarah Barlow, St. Louis, MO; William Cochran, Danville, PA; George Fuchs, Little Rock, AR; William Klish, Houston, TX; Nancy Krebs, Denver, CO; Richard Strauss, Titusville, NJ; Andrew Tershakovec, Philadelphia, PA; John Udall, New Orleans, LA

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) Web site.

Print copies: Available from NASPGHAN, PO Box 6, Flourtown, PA 19031; Telephone (215) 233-0808; Fax (215) 233-3939; E-mail naspghan@naspghan.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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